



UNITED STATES PATENT AND TRADEMARK OFFICE

W
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/017,798 | 12/12/2001 | Valentin Kramer | 31567.3 | 9144 |
| 27683 | 7590 | 08/19/2004 | | |
| | | | EXAMINER | |
| | | | CHANG, VICTOR S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1771 | |

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|----------------------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/017,798 | KRAMER ET AL. | |
| | Examiner Victor S Chang | Art Unit 1771 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01 July 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-18 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-18 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Introduction

1. The Examiner has carefully considered Applicants' amendments and remarks filed on 7/1/2004. Applicants' amendments to the specification, claims 1-4, 10-13 and 15-17 have been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Rejections not maintained are withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

More particularly, the amended independent claims 1 and 10 now recite, *inter alia*, "expanded PTFE is created ... above a melt-point of the PTFE" and "expanding ... PTFE ... above a melt point of ... PTFE", respectively. However, Applicants fail to

provide specific support that how a polymer such as PTFE can be stretched into a porous structure while the temperature is above its melt point. In other word, it lacks enablement to one of ordinary skill in the art to perform the stretching process step while the polymer is in a melt state (above its melt point). Evidentiary support is requested.

6. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

More particularly, the amended independent claims 1 and 10 now recite, *inter alia*, "expanded PTFE is created ... above a melt-point of the PTFE" and "expanding ... PTFE ... above a melt point of ... PTFE". However, the specification only teaches "expanded ... at about the melt point of the PTFE of about 350°C." (specification, page 6, lines 30-32). As such, clearly the scope of the amendment is not commensurate with the specification, and appears to be new matter.

7. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, substantially for the reasons set forth in section 3 of Paper No. 112403, together with the following additional observations.

It is noted that independent claims 1, 10 and 17 have been amended in an attempt to clarify the scope of the first and second pore size distributions. Additionally,

a new process limitation “expanded PTFE is created at a temperature above a melt-point of the PTFE” is incorporated in claims 1 and 10. Further, claim 17 now recites the ranges of pore sizes of the first and second series of major nodes, and a new process limitation “PTFE article is formed by expansion at a temperature near a melt-point of the PTFE”.

In response, the Examiner notes that while the claims are substantially amended, many claims are still replete with vague and indefinite recitations. In particular, the Examiner repeats (see Office action dated 4/1/2004, section 4) that it is unclear as to how the scopes of the two vaguely recited “pore size distributions” can be patentably distinct, because in the absence of a distinct limitations regarding the first and second “pore size distributions”, it appears that any substantially uniform distribution of pores over a range of pore sizes could be arbitrarily further randomly subdivided locally into “distributions” of different pore sizes, which are “intermixed” within each other, and as such reads upon the instantly claimed invention. Clarification is again requested.

Response to Amendment

8. Claims 1-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0 402 901 in view of Applicants' admission, substantially for the reasons set forth in section 5 of Office action dated 4/1/2004, together with the following additional observations.

First, the Examiner reiterates the relied upon prior art as follows:

EP '901 (an equivalent to the DE 690 03 879 reference, which is previously relied upon in Office action dated 4/1/2004) is directed to a PTFE porous material comprising a mixture of PTFE having a high molecular weight of 2,000,000 or more and a low molecular weight of 1,000,000 or less. The material having been stretched at least uniaxially (Abstract). In Examples 1-4, EP '901 shows a mixture of high and low molecular weight PTFE fine powder, and further mixed with a liquid lubricant. The resulting mixture is extruded with a paste extruder, formed into a sheet, and expanded in a heated machine by uniaxial or biaxial stretching in an atmosphere of about 330°C. Further, Applicants appear to have admitted that it is known that the pore sizes of the of the PTFE-material can be varied by changing the mixing ratio between the high molecular weight PTFE and the low molecular weight PTFE; and the PTFE-material can exhibit different shapes, for example a foil, sheet or cube (specification, page 1, lines 14-21). Applicants also admitted that many similar designs of ePTFE tubes serving as vascular grafts can be found in the market place, and it is known that uniaxially expanded ePTFE tube can be reinforced with a ring complex (specification, page 1, lines 27-33).

Applicants' argument "DE 690 03 879 fails to teach or suggest every element of amended claims 1, 10 and 17. For example, the claims as amended recite that the PTFE is expanded at a temperature near or above a melt-point of the PTFE ... the DE 690 03 879 reference fails to meet the standard required by MPEP 2131 and 2143 ..." (Remarks, pages 7-8, bridging paragraph) has been carefully considered, but is not persuasive. First, for claims 1-16, the Examiner notes that Applicant must show that the

resultant article is patentably distinct from those taught by the reference, since the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation at the present time has not been given patentable weight. It should be noted that product-by-process claims are product claims and that to be limiting in a product claim, a process limitation must be evidenced as effecting the structure or chemistry of the resultant product over the prior art. Further, the burden of proof for this showing is on Applicant after the Examiner presents an otherwise *prima facie* rejection. See MPEP § 2113. Second, for claims 17 and 18, the Examiner notes that EP '901 expressly teaches in Examples 2 and 4 that the stretching process is carried out in an atmosphere of about 330°C (near melt point of PTFE), as set forth above, Applicants' argument to the contrary notwithstanding. As to the newly recited ranges of pore sizes of the first and second series of major nodes in claim 17, the Examiner repeats (see Office action dated 12/1/2003, page 4) that although the EP '901 lacks an express teaching of the pore size distribution, it is noted that the scope of the EP '901, in particular the use of mixture of PTFE having high and low molecular weights to modify the pore sizes, and its manufacturing process, are essentially the same as the instantly claimed invention. As such, in the absence of unexpected results, it is believed that suitable pore size distributions are either anticipated, or an obvious optimization to one of ordinary skill in the art, motivated by the desire to obtain a suitable porous PTFE material. It should be noted that where the claimed and prior art products are shown to be identical or substantially identical in structure or composition, or are produced by

identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See MPEP § 2112.01.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In addition, the following references are cited of interest for making PTFE microporous membrane:

US 5102921 to Harada et al. is an equivalent U.S. Patent issued to the same inventor of DE '879.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VSC

Victor S Chang
Examiner
Art Unit 1771

8/8/2004



TERREL MORRIS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700